#### **EXHIBIT 141**

#### **EXHIBIT FILED UNDER SEAL**

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Date: Tuesday, June 3 2014 11:39 PM

Subject: Fwd: May BOD update

From: Riaz Valani

To: Zach Frankel

Attachments: 14-05 BOD Update.pdf; ATT00001.htm; 2014-05-20 FDA Guidelines and Ploom Impact.pdf; ATT00002.htm



#### Begin forwarded message:

From: "James Monsees" < james@ploom.com>

To: "Adam Bowen" < adam@ploom.com >, "Riaz Valani" < rvalani@gacapital.com >, "Nicholas J. Pritzker" < nick@taocap.com >, "Pirard, Eddy" < eddy.pirard@jti.com >, "Langner, Klaus D" < klaus.langner@jti.com >

Cc: "Daniel Hansen" <<u>dhansen@mh-llp.com</u>>, "Ralph Eschenbach" <<u>ralph@eschenbach1982.com</u>>, "Joby Pritzker" <<u>joby@taocap.com</u>>

Subject: May BOD update

All,

Attached please find the May BOD Update. I encouraged each department to more clearly communicate metrics and action items, which is the reason why there was no update in April. Since the next board meeting is early next month there will also be no June update to allow each department to prepare board slides. Please consider this the general format for the deck during the upcoming board meeting. Please let me know within the next few weeks if you'd like to see additional detail beyond what is communicated here for the board meeting. Of course I'll include some additional information regardless including an updated SWOT analysis and function report card.

In addition, please also find the most recent iteration of Ploom's analysis of FDA deeming regulation impact for your review.

Eddy and Klaus, I'm not sending this information to anyone else at JTI since this is BOD material. If you deem appropriate to forward portions or all of this deck to specific people inside JTI please feel free to do so at your discretion.

Questions or comments of all sorts welcome as always. Thanks.

-James

James Monsees ceo

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BOD update

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### key points

device in China and the JUULpods in Hong Kong using primarily manual methods to start. Key needs are to receive the JUUL agreements and business plan from JTI and refine US volume expectations based upon selective trade receptivity under NDA. Liquid chemistry patent filled. Phase O clinical trial results complete with exceptional results. JUU.pod prototypes are yielding considerably more vapor per puff than any small form factor competitor. End of June should see fully functional prototypes without leaking issues. Device and JUU.pod will then be increased in size slightly for better market positioning. Development is on schedule. General manufacturing plan is identified, with Defond to manufacture the

prepared and circulated broadly. Ex-banker consultant has been brought on to assist in data room prep and materials refinement. Backfill interest from high profile individuals and value-add investors is likely at or beyond the size of the round. Several potential lead structures are in discussions. Expect a lead to be identified in the next 4-6 weeks and for the process to accelerate from there. Fundraising process is progressing smoothly. Primary and secondary materials for fundraising have been

#### Supply Chain and Forecasting

resolved. Pod supply outstanding PO issues have been resolved with JTI. Ploom is holding approximately \$1.4M in excess components across all product categories, most of which will be drawn down with subsequent manufacturing needs. Ploom is holding approximately 80K excess M2 finished goods devices in excess of demand due to the transition to M3, expecting most of this to be written down in 2015. Forecasting has been right-sized and controlled. Defond excess component inventory situation has been

Our new CFO John Franzino has signed on and begins June 16th.

The CMO role is being redefined generally as a C-level "growth lead" to oversee marketing and sales. The search will resume following John's start so he can participate.

from JTI. Device testing at elevated temperatures for VG-heavy pod formulation compatibility is showing Mouthpiece ergonomics and condensation have been considerably improved based in part on feedback high confidence for launch. Despite the higher operating temperature, mouthplece operating temperature is reduced with VG-heavy formulation. On track for Q4 launch. Key issue is to identify VG-heavy pod launch timing with JTI, but this won't impact device launch timing.

PAX2 Alpha prototypes are complete and very well received internally. Product heats up considerably faster and successfully addresses all major identified issues with PAXI. Product development is on schedule for Q1 2015 launch so that PAX1 inventory can be drawn down over the 2014 holiday season.

New heater technologies have shown the capability to reach sub-3 second heat up times reliably and consistently. Considerably more engineering development is still needed to move these results to a manufacturable design. Sachet-type consumables will begin testing soon.

Privileged information regarding ongoing actions continue to be communicated separately.

US sales are slightly above forecast. Approximately 50 new activations. Still no substantial pull-through information on M2 but distributor and wholesale account diversification is clearly growing substantially. Approximately 3000 additional PAX accounts, primarily in CTS channels over this time last year. Compliance continues to improve as internal capabilities are ramping up. Key need is to continue to decrease dependence on outside counsel and get to fully compliant status-quo in 2014. TTB importer Customer base diversification is outpacing revenue diversification. Expecting strong revenue diversification from JUUL introduction, as accounts are being well positioned for that launch.

Won a judgment against iPloom and the individual behind it, Anthony Marino, for \$500K plus legal costs. Unlikely we'll see much of this money but it's a strong precedent. Continuing to further deepen relationships with DH Gate, Alibaba and other gateway e-commerce

#### PAX Counterfeiting

application will be delayed as a result of adding the new CFO as a director.

Executive compensation ratified and finalized. Last round of option issuances ratified and finalized. Awaiting signatures from JTI UK management to ratify agreed option pool increase. Comp and options

Separate accounts set up for JUUL, well in advance of need. No major issues with merchant services, and website backend is running smoothly. Backup merchant providers are in place for each product line.

#### JTI Reimbursements

Merchant Services

Issue has been resolved.

#### Cash Flow

Cash position continues to improve and is on track as planned to hit EOY targets.

#### Budgets

Departmental budgets have been finalized and are being tracked monthly to actuals

#### **Operational Tools**

ERP and CRM systems have been initiated and should be operational by Q4. Expecting increased efficiency, communication and tracking capabilities

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## finance

under rapid growth. Through the ongoing creation of Finance is the stabilizing force of the organization, ensuring financial operating capability, particularly structured process finance addresses: Management and periodic assessment of Ploom's five-year strategic business plan

Development and adherence of departmental budgets

Continued Cash Flow management

Cost containment

Ongoing regulatory compliance

Accurate record keeping

### key learnings

The existing team is operationally-focused with minimal bandwidth. This limits the ability to provide strategic, holistic direction the company requires.

Cash management has stabilized. Continued focus ensures Ploom will improve its cash and overall financial position in the current year In a rapidly growing environment the company has clearly been consistently under capitalized.

### key initiatives

CFO hire - this critical role will develop and execute the overall business and financial strategy of Ploom. John Franzino accepted, begins June 16th.

Continuing to refine and validate forward-looking scenario planning for market

Strict budgetary adherence and other control processes and procedures to support sound operations necessary as the company continues to grow

Continuing to bring in-house the appropriate resources in addition to sourcing the necessary expertise required to support operations Selection and implementation of a robust and sophisticated accounting/ERP solution, enabling improved efficiencies in record keeping and enhanced reporting capabilities

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\$4,225,583

## finance

We have a candidate recommendation under consideration by the board. John Franzino, former CFO of Santa Fe Natural Tobacco Company

## Forward-looking scenario planning

market capture. At present, we are continuing to gather and synthesize e-Cig Ploom continues to refine and validate forward-looking scenario planning for market research in order to validate the potential market for JUUL.

## Budgetary adherence and other control processes

We continue to develop and apply processes to manage expenditures as well as ensure consistency in on boarding new customers.

addressed with the appropriate department head (see chart on right for further spending patterns were being managed properly and any material issues were Our cross departmental review of Q1 spend to Q1 budget confirmed that

#### Finance resources

We continue build out our team to manage the needs of the department, with the CFO role being our first priority. In addition, we continue to source the necessary expertise required to support operations.

We are in the final stages of selecting an accounting/ERP solution. The finance department has made specific requests of potential vendors to understand further the capabilities of the systems and how those suit the needs of the department. We are awaiting review.

### Q1 2014 Actual to Forecast

Department	Forecast	Actual	%
Employee	1,552,668	1,333,537	86%
Sales + Distribution	1,628,676	196,176	%09
Marketing	925,501	366,145	40%
Engineering	239,500	302,627	126%
R&D	225,000	435,127	193%
RMA/Warranty	156,000	159,423	102%
G&A	399,829	527,368	132%
Travel & Entertainment	155,856	129,365	83%

Employee spend anticipated C-level hires occurring in early Q1.

\$5,283,030

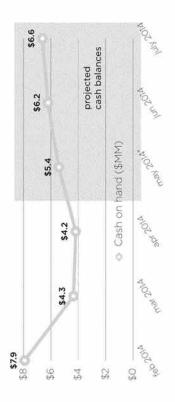
In response to CF considerations in Q1, revenue-driving departments (Sales and Marketing) operated in line with Q4 actuals vs. budget. Q2 spend will follow

R&D excess spend is primarily attributable to regulatory legal spend. Spend in this area will be more appropriately managed in future quarters.

63% of T&E is Sales team driven and in line with budget.

# financial dashboard as of April 30, 2014

### Combined Cash on Hand: \$4.2MM



Cash balances declined to their lowest point in April as Ploom continued to make payments towards Defond negotiated balances, including an additional \$11MM relating to component balances.

Cash balances have improved in the first half of May due to distributor revenues exceeding projections, timely receipt of receivables, and continued careful management of cash expenditures.

Given sales projections coupled with estimated spends, we anticipate cash balances will exceed \$6MM by end of Q2.

Royalty Receivable: \$17.5K Based on JTI reporting through March 2014

### Inventory - March 31: \$12.3MM

components inventory resident at Defond. As of May 19, Finished Goods balances Inventory balances of \$12.3MM include \$1MM in Raw Materials, reflecting M2/M3 are \$11.9M; we expect PAX inventory balances to normalize by Q3. There is no expectation of a draw down in components in the coming quarter.

## A/R Aging of Material Balances

Ct.						
	Current	1-30	31 - 60	61 - 90	<b>06 &lt;</b>	TOTAL
,	94,196	10.00			500000000000000000000000000000000000000	54,196
JTL 5.	4,784	47,745	į	ï	20,000	122,529
Kretek Int'l 32	328,800	, i	į	,	ī	328,800
Sheetz, Inc 32	329,761	,	į	,	į	329,761
South Bay Wholesale 4	3,685		i	ï	į	43,685
Warehouse Goods 3,7	737,215	197,630	ï	ik	ě	3,934,845
\$4.5	4,548,441	\$245,375	\$0	\$0	\$20,000	\$4,813,816

Notes as of May 19, 2014:

(1) JTI balances do not include balances relative to the Reimbursement.

### A/P Aging of Material Balances

	Current	1 - 30	31 - 60	61 - 90	> 90	TOTAL
DEL Enterprises	2,058,956	v	ø	B¥	æ	2,058,956
Genhon (1)	53,787	í	ą	à	ī	53,787
Kuehne+Nagel (2)	67,201	5	ì	:5	1	67,201
NMS (3)	148,724	i.	à	à		148,724
WSGR (4)	44,809	1.		ı.	1	44,809
TOTAL	\$2,373,477	\$0	\$0	\$0	\$0	\$2,373,477

Final payment relative to the negotiated balances with DEL were made in the first half of April. At present, all DEL balances are current and reflect current ordering and engineering needs.

Filed 02/12/25

- (1) Soft Finished Goods (M2/PAX sleeves...)
  (2) Logistics
  (3) Inventory management
  (4) Legal regulatory

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### MDL RV0000261

## marketing

Deliver growth and drive revenue by acquiring and maintaining retailer interest and consumer conversions

modelTwo - Drive sales at brick & mortar level and ensure consumer satisfaction

Pax - Maintain sales growth

Launches - Develop launch strategies for modelThree, Pax 2 and Juul

#### key learnings

modelTwo is a complex product offering that requires educational messaging

Expectations of modelTwo need to be managed to ensure consumer satisfaction

Pax has achieved saturation within a niche consumer base

Potential for expanding Pax consumer base lies with growing tobacco consumer base

#### key initiatives

Message modelTwo product promise

Improve modelTwo product experience for consumers

Communicate how to sell modelTwo / drive pull-through

Develop modelThree launch strategy

Improve content distribution to increase mainstream awareness of Pax

Promote Blend X to grow tobacco consumer base

Establish product, consumer and market learnings for Juul go-to-market strategy

Develop go-to-market strategy for Pax 2

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MEET PLOOM

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# marketing: key initiatives drivers

Communicate how to sell modelTwo / drive pull-through

- Rebooting all sales materials to more clearly and concisely communicate how to achieve modelTwo sales
  - Testing variety of retailer POS/promotions/offers
- Testing ways to better utilize events to drive sales

## Benchmark: complete tests and perform analysis by modelThree launch

Message modelTwo product promise

- Developing and testing brand messaging alternatives to "Rethink Tobacco" - Secured new though-leader PR firm to place CEO bylined articles to drive
- Increased focus on business press for greater modelTwo product education increased messaging impressions and help refine messaging
  - Benchmark: target % growth in number of placements achieved

Improve modelTwo product experience for consumers

- Utilizing new 6-second videos and new Pro Tips card to better communicate
- Utilizing web programmers for better modelTwo consumer data to guide messaging and strategy and exploring additional vendors
  - Working on ploom.com reboot to make it easier for consumers to find
    - information

Benchmark: site reboot by modelThree launch

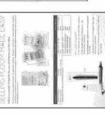
Develop modelThree launch strategy

- Aligned with sales, customer service, engineering and supply
- All messaging and assets needed for launch PR, sales decks, Ploom.com
  - Tradeshow and trade advertising strategy

Benchmark: complete tests and perform analysis by modelThree launch

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"The sleek, modern, minimalist design of both modelTwo and Pax make them as much a high-tech





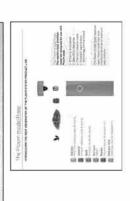


"The glowing gadgets









# marketing: key initiatives drivers

Improve content distribution to increase Pax mainstream awareness

- Online ads are increasingly driving revenue, so increase in spend is merited
  - Tying content distribution to event related spends
- Exploring paid video distribution platforms

Benchmark: target % growth in ploom.com sales, video views and audience

Promote Blend X to grow tobacco consumer base

- Sell sheet and retailer POS
- Social media and newsletter campaign
  - Blend X specific PR pitching
- Introducing new Blend X SKUs for more comprehensive and compelling offering

## Benchmark: target % growth in ploom.com sales and number of placements achieved

Develop go-to-market strategy for Pax 2

- Product launch task force exploring pricing and timing
  - HoReCa (Hotel/Restaurant/Cafe) tests:
- Casino/hotel gift shop, minibar, bottle service, pool/beach cabana menus
- Setting up test partnerships with SBE Group at SLS Vegas and SLS Miami
- ID'ing opportunities to tie marketing spends to sales distribution placements
  - Exploring additional distributors to better facilitate HoReCa orders
     Benchmark: complete tests and perform analysis by end of calendar year

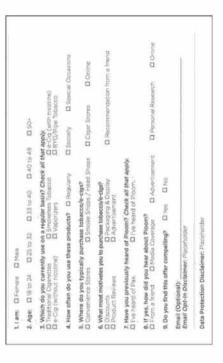
Establish learnings for Juul go-to-market strategy

- Sheetz consumer survey to generate consumer data
- Currently analyzing additional consumer insight gathering tactics

Benchmark: complete tests and perform analysis by end of calendar year

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## marketing: brand building

Brand-guided companies on average, have profit margins nearly twice their respective industry average

recommended by a brand advocate 61% of consumers consider buying the brand, product or service

friends, family and co-workers 90 times each week A consumer mentions specific brands in conversations with

The Top 100 Most Powerful Brands outperformed the S&P 500 by 37% between 2006 and 2011

\*Source: prophet.com/sites/strongbrands/

pa plaam XX

It's been nearly 2 years since the Pax brand debuted.

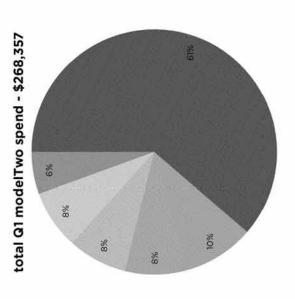
first enter the site directly through the Pax product On average today, over 65% of ploom.com visitors landing page, the vast majority through organic searches. Though it's difficult to directly attribute dollars, the influence of brand-building efforts on revenue over time is unquestionable.

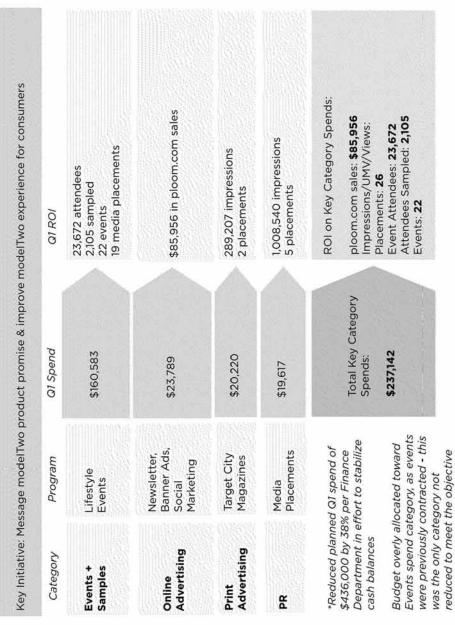
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# marketing: modelTwo Q1 spend & ROI







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# marketing: modelTwo budget pivot

**Opportunity budget** - Reallocating remaining budget toward marketing support in Sales target cities, consumer research, large-scale activation test(s)

distributor and retail support, fulfillment materials

retargeting ads into display advertising program

budget per ROI results, savings by rolling

Reduce to \$175,000 - reduced social marketing

captured with Sales and Global Supply budgets -

Collateral

Reduce to \$7,000 - previous spends are now

Advertising Online Print PR Other includes Design, Samples, Video, Photography, Collateral Events
Print Advertising
Opportunity
Online Advertising
Website Influencer Travel Online Advertising = 17% Print Advertising = 15% PR = 8% Influencer = 6% Photography = 1% Samples = 4% Design = 3% Travel = 3% Video = 1% Website = 6% Collateral = 4% Events = 35%

Website
PR
Travel
Influencer
Other includes Design, Samples, Video,
Photography, Collateral
adjusted 2014 Budget

7%
4%
7%
14%
17%

initial 2014 Budget - \$1,743,074

3% 3%1%%

4%

969

%9

Reduce to \$15,000 - savings generated by utilizing Field Marketing Manager hire - no longer utilizing Reduce to \$70,000 - savings generated by new Increase to \$300,000 - value add opportunities **Decrease to \$100,000** - cut target city local PR firms, cut event publicist spends in H1 Increase to \$75,000 - increased team size and Reduce to \$30,000 - Field Marketing Manager influencer agency for on-site management increased focus on Sales field information reviewing program to tighten spend through buys for events and online renderings Photography Influencer Samples Travel

gathering

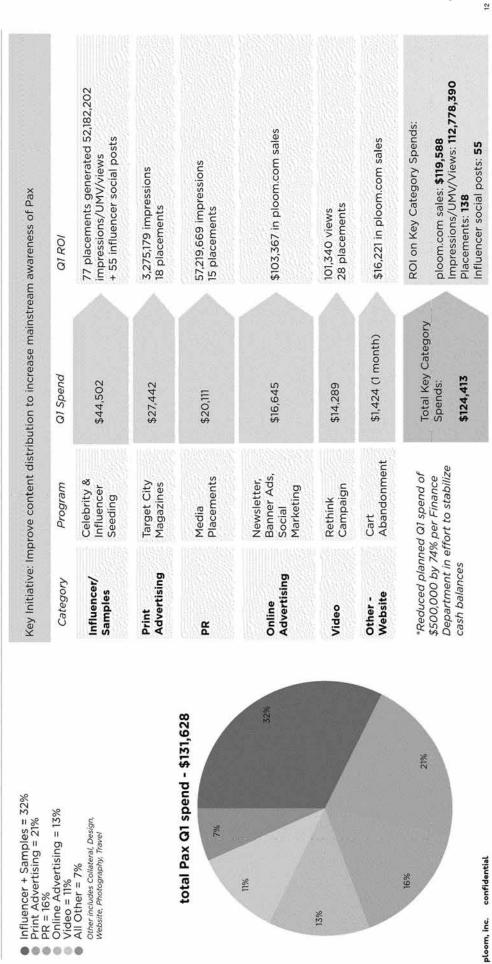
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17%

15%

8%

# marketing: Pax Q1 spend & ROI



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## marketing: Pax budget pivot

Opportunity budget - Reallocating remaining budget to gain learnings in preparation for Pax 2 launch: marketing support in Sales target cities, consumer research, largescale activation test(s)

Online Advertising = 30%

Samples = 12% Print Advertising = 11% Video = 10%

Influencer = 8% Collateral = 6% Design = 5% Website = 5%

Events = 5%

Photography = 3% Travel = 3%

intitial 2014 Pax budget - \$2,000,000

3% 3% 3% 2%

%9 2% 12% 11%

2%

5%

adjusted 2014 Pax Budget Opportunity = 36%
Online Advertising = 18%
Print Advertising = 11%
Events = 6% Photography, Travel, Samples Other includes Collateral, 4% Influencer = 5% Design = 5% Website = 5% Video = 5% Other = 4%

PR

18% 2% 11% 2%

Samples

distributor and retail support, fulfillment materials captured with Sales and Global Supply budgets -Reduce to \$7,000 - previous spends are now

Collateral

retargeting ads into display advertising program, savings also generated as content production for Reduce to \$350,000 - reduced social marketing Pax is value add from modelTwo event spends budget per ROI results, savings by rolling

Advertising

Online

Reduce to \$100,000 - savings generated as video distribution captured within Online Advertising

Video

PR = 5%

000

firm better positioned to manage upcoming launch Increase to \$100,000 - transitioning to new PR and business press needs

Reduce to \$15,000 - savings generated by anticipated assets shared by JTI

**Photography** 

Field Marketing Manager hire - no longer utilizing Reduce to \$100,000 - savings generated by new influencer agency for on-site management

Influencer

Reduce to \$125,000 - Field Marketing Manager reviewing program to tighten spend

transitioned majority of event dollars to modelTwo Reduce to \$50,000 - Ploom sampling strategy

Event

Travel

Reduce to \$15,000 - reduced event-related travel

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10%

8%

#### sales

Develop credibility in the retail and wholesale marketplace by introducing Ploom Inc. and its products to influential retailers and distributors

Commercialize Pax and modelTwo + pods by targeting a select group of trade partners for initial distribution

Groom new trade relations for future juul sales

#### key learnings

initial activation strategies showing positive results	modelTwo + pods account for majority of new customer revenue	customer base diversification outpacing revenue diversification	modelTwo requires greater-than-expected in-store incubation, and is delivering less- than-expected rates of sale
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#### key initiatives

deliver \$48M sales revenue	expand pax distribution base	launch modelTwo via small-scale test initiatives	groom long-term strategic trade relations	develop and grow sales team to deliver key initiatives
deliver	expand	launch modelTwo	groom long-te	develop and grow sa

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## sales: key initiative update

#### \$48M sales revenue

and +\$2M (+15%) ahead of plan. April revenue was +84% over last April and +42% \$48M by end of year. YTD revenue of \$15.3M is +\$6.7M (+79%) ahead of last year YTD revenue is trending ahead of plan, and is on track to be at, or above, plan of over plan driven by atypically large WHG orders to right-size inventory levels.

contributing 4% of total revenue. Alternatively, new customer revenue accounts dollars. However, revenue is beginning to diversify with modelTwo + pods Pax and related accessories dominate revenue accounting for 96% of total for 5% of total revenue.

## pax channel distribution expansion

the 45 new trade activations. As vaporization becomes more mainstream, we are Pax is gaining incremental traction, and proving viable, in the CTS channel. Initial CTS test has been expanded from 14 stores to 50 stores. Additionally, Pax has been activated in an additional 4 regional CTS chains. Most encouraging is that Pax is benefitting from modelTwo trade activations as Pax is included in 42 of distribution in select stores. Pax is on-track to reach the goal of 7,000 total experiencing some early interest from the convenience channel to test Pax outlets by end-of-year.

#### modelTwo launch

\$705k new customer revenue—in stark contrast to overall Ploom revenue ratio of ModelTwo + pods is included in 44 of the 45 trade activations. ModelTwo is now additional targeted chain store tests. New customers overall account for 81% of being purchased by 13 customers in addition to online sales. The initial test has total \$612K modelTwo revenue. Conversely, modelTwo comprises 71% of total been expanded from 14 to 30 stores, and modelTwo is now being sold in 4 Initial activation strategies are beginning to deliver measurable results. 4% /96% (modelTwo / Pax).

progress towards gaining distribution whereas unaided distributors and retailers Post initial distribution, modelTwo requires significant in-store support at launch such that unaided sales models are ineffective. Ploom field sales are making anticipated sales rates which necessitates an immediate need to increase have had little to no success. Early sell-thru data points to slower-thanvelocities thru additional promotion vehicles.

### trade relation development

wholesalers that control over 60% of the tobacco market. The trade has been propositions. The sales team is actively grooming these relations for existing very receptive to the company, its products, and their relative unique selling product sales as well as future juul sales. Progress against this initiative has To date, Ploom has been introduced to a combination of retailers and exceeded expectations and bodes well for early juul activations.

#### sales team development

additional regional distributors that support the local independent class of trade. three field sales teams are now fully-populated with the New York team starting consuming than expected which further supports the need for a directly aided on April 28. Field management has been focused on activating the market via The field teams are on-track to reach their stated distribution objective of 200 The sales team has grown to 16 (12 field, 2 strategic accounts, 2 internal) The accounts per sales person. ModelTwo sell-in and activation is more time go-to-market approach.

The strategic account team is overseeing the vast majority of the 45 trade retail and trade activations. Upcoming sales team additions will be focused on (in order of priority) increasing key account management and opportunistically building out the existing three field teams.

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increased interest from major convenience chains Ploom viewed by trade as highly differentiated

relations in advance of juul

# sales: strategic phase (A) progress

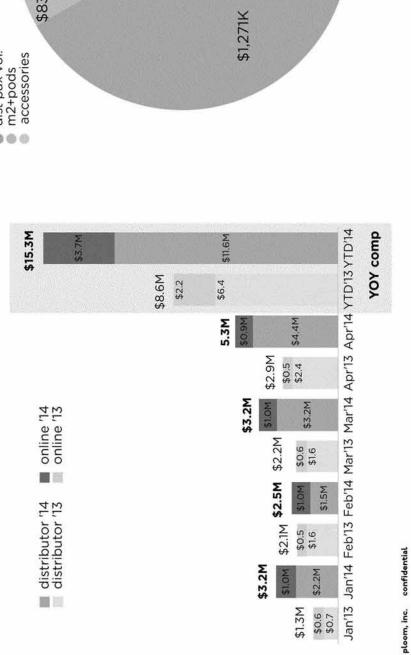
wholesalers and retailers resulting in no MSRP increase. This will deliver approximately +\$5M in 2014 gross revenue. Ploom has been introduced to 45 trade partners to-date setting the stage for a successful juul launch and allowing for pax distribution expansion and model theTwo test launch. Sales most notable contributions to-date are the Pax list price increase and the 45 trade activations. The \$20 Pax list price increase was wholly absorbed by

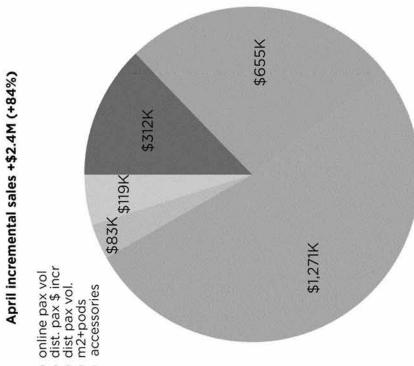
introduced to accounts controlling > 60% tobacco mkt. LA & SF field teams added 143 new distribution points +\$20/device generated +\$655K April gross revenue sales rates increasing in initial CTS test stores all trade activations are applicable to juul progress included in 42/45 new trade activations included in 44/45 new trade activations activated in 4 additional CTS chains activated in 4 additional CTS chains 11/13 new customers purchasing tobacco channel and improve launch modelTwo + pods via expand Pax into specialty small-scale test initiatives develop strategic account strategy margin 3 2

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## YTD gross revenue comparison

YOY sales revenue vs. LY





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Oec

404

oct

Sep

AUG

W

m

Nay

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Nat

4elo

Jan

\$8.3M

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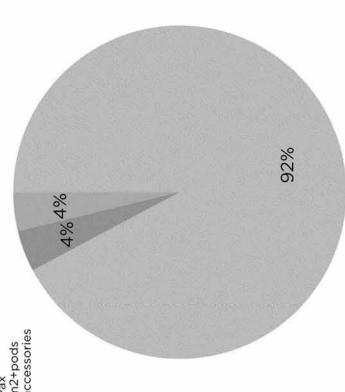
## YTD revenue metrics

## YTD sales revenue by product category

- pax remains dominant revenue driver
   revenue beginning to diversify with m2 + pods
   small-scale of m2 initiatives combining for low percentage of total revenue



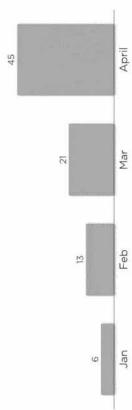




YTD sales metrics • 2014 sales metrics reflect progress against key initiatives

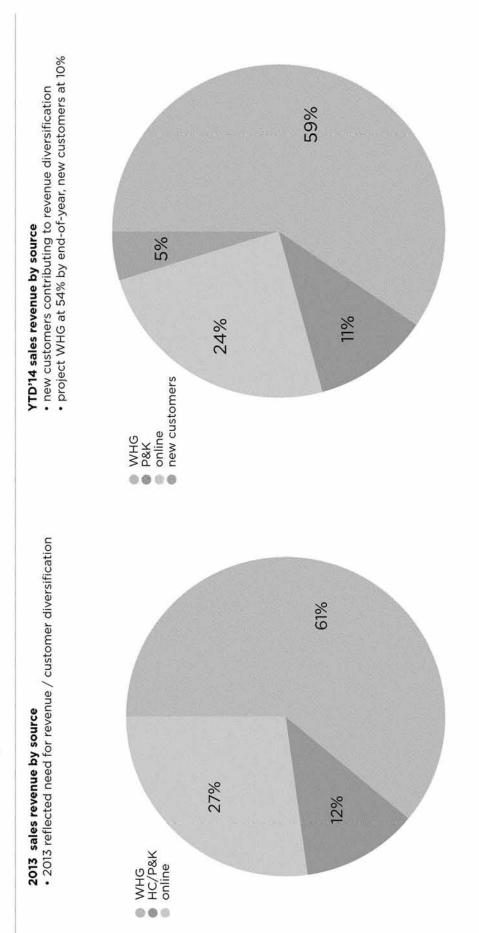
2014 YTD	93,183	94,696	606'6	51	366	91	45
2013 LYTD	65,055	0	0	2	0	0	0
metric	pax volume	pod pack volume	m2 device volume	ship-to customers	A SF field placements	ploom sales team	trade activations

cumulative trade activations



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## YTD revenue by source

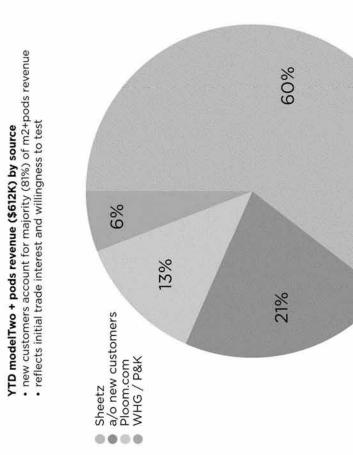


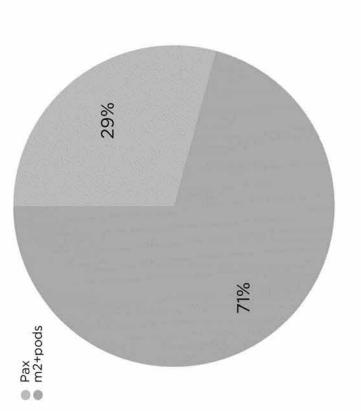
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## YTD new customer revenue

## YTD new customer sales revenue (\$705K) by product category • new customer revenue reflects progress against m2 launch strategy • m2+pods account for majority (71%) of new customer revenue • new customer pax/m2 revenue ratio 29/71 vs. total Ploom 96/4





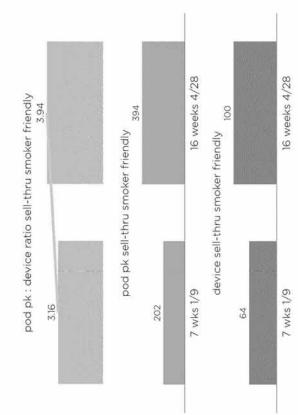
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MDL RV0000277

## new customer pod pack sales

## pod pack sell-thru CTS Smoker Friendly test

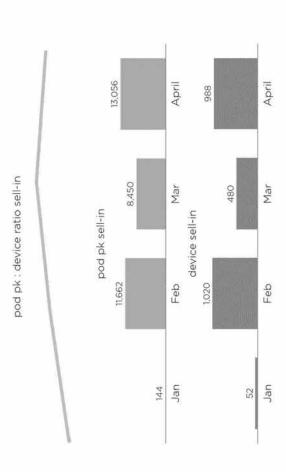
- increasing pod/device ratio between periods indicating existence of some stable user base
- · overall velocities declined between periods reflecting the need to increase rates-of-sale
- period ending 1/9 saw greater in-store promotion activity



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## pod pack sell-in for all other (a/o) new customers (excl. Sheetz\*)

- initial sales trends relatively stable
- increasing pod pack sales to devices thru March
- · majority of sales reflect initial sell-in for pre-sold retail accounts
  - sell-thru to-be-reflected in future reorder patterns
- next steps are to analyze reorder patterns vs. sell-in
- \*Sheetz data excluded due to large pipeline fill quantities



## global supply

GSC supports the key manufacturing requirements of world-class innovative products by:

- Ensuring on-time delivery of high-quality, finished goods while minimizing costs.
- Ensuring manufacturing capabilities for existing and future products
- Balancing inventory to provide flexibility and corporate optionality.
- Supporting continuous improvement of products through Ploom's quality program.

### key learnings

Ploom's fast growth necessitates processes, protocols, checks and balances in order to maximize efficiency of resources

Case 3:19-md-02913-WHO

Data integrity and consistency yields a more accurate and robust demand planning system Demand is a business planning activity that requires cross-functional collaboration

Streamlining the JTI / Defond relationship will dramatically improve Ploom's ability to grow and streamline its own business

### key initiatives

JUUL supply chain strategy

M3, PAX2 Product transitions - supply chain strategies

JTI / Defond Supply Agreement (subordinate to Ploom / Defond agreement) Legal and financial framework with JTI and Defond for management of surplus components and future orders

ERP implementation - prep internal S&OP processes and back-end data for smoother transition Continuous improvement through defect analysis and collaboration with Defond's engineering and quality teams

Right-size PAX and M2 inventory for 2014

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## global supply chain

### JUUL Supply Chain Strategy

requirements and infrastructure that will be needed to supply JUUL. This is an on-GS is coordinating with Engineering and R&D to understand the supply chain

### M3 and PAX2 Product Transitions

M2 to M3 transition - Current strategy calls for launch of M3 in October 2014. It will be be managed, and Ploom will determine whether a write-off will be necessary. The M2 launched independent of the release of a new pod formulation. Excess M2 stock will gaining traction in the US market, and it is difficult at this time to predict sales

any longer. Demand planning will shift to the ONYX (black) and COBALT (blue) colors, performance in Q4 for this product. PAX1 to PAX2 transition - Ploom expects to sell out of AMETHYST (PURPLE) PAX by Q3 2014, and there is no plan to purchase AMETHYST (purple) or EMERALD (green) and we expect to have some level of inventory as we launch PAX2 in Q1 2015.

### JTI and Defond Supply Agreement

JTI and Defond have a working de facto relationship for which Ploom is currently the framework for which JTI can work directly with Defond. This would allow JTI greater freedom to manage its demand planning and production, while Ploom remains the intermediary. Ploom and JTI are collaborating to understand a legal and financial design center for all Ploom product lines.

#### **Surplus Components**

committed to helping Ploom and Defond account for excess components by working Defond. Ploom is actively working with Defond to mitigate component exposures on out a legal, financial, and logistical framework for managing components. There is a components by end of 2014, with transition to PAX2 scheduled for Q1 2015. JTI has portion of components that can be used for future product lines, as well, and this is M2 as obsolescence is planned in Q3 2014. Ploom will work through PAX excess JTI continues to be a pro-active partner in addressing component exposures at part of the calculus for managing these materials.

#### ERP System for Ploom

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An internal inventory planning model was developed and implemented in Jan 2014 to centralize inventory, sales, and forecast data, providing higher accuracy and higher resolution. This is the interim solution until ERP implementation

The GSC team is set to adopt, implement, and manage a world-class, cloud-based ERP system that will provide greater accuracy and intelligence for how Ploom manages its

### Warranty and Quality Program

that the findings are being fed back into the design of PAX2. Many of the issues that data for PAX defects has yielded substantive results that have improved accuracy for on-line quality checks. GSC has also bridged customer service with engineering so Key investigations into technical problems on the PAX, and an analysis of historical we have identified have been addressed by the PAX2 design team. And Ploom continues to work with Defond's engineering and quality teams to improve the

faster than expected. Current monthly sales rates are averaging at or around 25,000 **PAX and M2 Inventory** PAX inventory in the USA has been achieved. Sales rates are units. There is no excess of PAX inventory.

Tobacco Pods - Ploom continues to right-size Pods inventory as it continues to expand footprint in the US market. M2 inventory is expected to be in excess at M3 launch. M2's footprint in the US market. Pods inventory is expected to be in excess at M3 M2 - Ploom continues to right-size M2 inventory as it continues to expand M2's

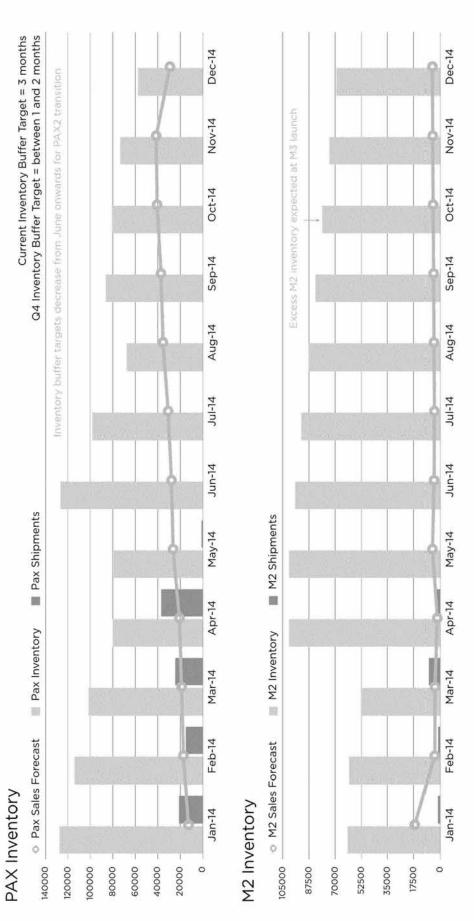
purchase orders being submitted accordingly. There is no excess of PAX accessories Accessories - Sales rates continue as expected for all PAX and M2 accessories, with

#### Personnel

Current head count: 4

- Operations Manager
- Warranty Quality Manager
  - Logistics Manager

# global supply chain - US inventory outlook



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## product design

brand identity of offering elegant, simple, and easy to PD creates innovative products that drive Ploom's use vaporization experiences.

development of products and accessories, including The PD group is responsible for all aspects of the industrial design, engineering, user interface, and packaging. PD also coordinates all required compliance and safety testing.

### key learnings

Additional staff are needed to support product growth. We will continue to evaluate key hires to help maintain aggressive schedules and improve product quality.

Juul prototype design meets vapor performance requirements, but needs refinement to eliminate leaking.

Pod products need to focus on increasing vapor production and quality.

People love Pax, so redesign should improve and expand, but not change the key usage paradigm.

### key initiatives

Perfecting Juulpod design by eliminating leaking issues and maximizing vapor performance.

Testing of higher temperature modelThree prototypes to support R&D effort to markedly increase pod vapor production and quality.

Development of Pax2 maintains existing Pax usage while offering significant product improvements.

Researching on-demand heating performance for loose-leaf vaporization product to maintain product leadership and expand product line offerings

Expanding the team where necessary to help ensure schedule adherence.

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Device

MDL RV0000283

More complex molding

chance of leaking

pod size, no visible degraded end of life performance

> Negatives Design

50% increase in liquid level,

optimal resulting Airflow is nonin lower vapor production

#### JuulPod

Issues with leaking at both atmosphere and pressure (e.g. on an airplane) are being addressed with a multiple design direction strategy.

tank to solve the leaking issue. Batting will require a 50% increase in pod Design 1 has a fiberglass tube air path, single wick, and a batting-filled performance. Preliminary prototypes received and on hold pending size, eliminate visible liquid level, and impact end-of-life pod testing of Designs 2 and 3.

maintains a liquid tank, two side air paths, improved sealing, and overflow areas to accommodate typical worst-case pressure scenarios (2 airplane trips). Preliminary testing average to poor vapor performance (2-3mg/ Design 2 is a refinement of the Alpha prototype pod design which puff). Pressure testing has not yet been conducted.

overflow areas to accommodate typical worst-case pressure scenarios (2 excellent vapor performance (8mg/puff, stable puff size over entire pod Design 3 has a liquid tank, with a central air path, improved sealing, and airplane trips). Preliminary testing shows good leak resistance and

Prototypes of Design 3 are being tooled to provide 5 devices/20 pods to JTI in late June.

progress to provide a minimum of 200 puffs based upon JTI's market Current designs provide 100-110 puffs at 4.5mg/puff. Redesign in research.

Fiberglass tube a path, batting to store liquid store liquid (e.g. Njoy)  Fewest leak issue doesn't require overflow tank		Fiberglass tube air paths, liquid tank, path, liquid tank, store liquid cap	Most disposables JoyE eRoll Combination of eRoll (e.g. Njoy)	Fewest leak issues, Design flexibility chance of leaking doesn't require Simplified molding resulting in excellent vapor performance	More sealing surfaces increase
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### modelThree

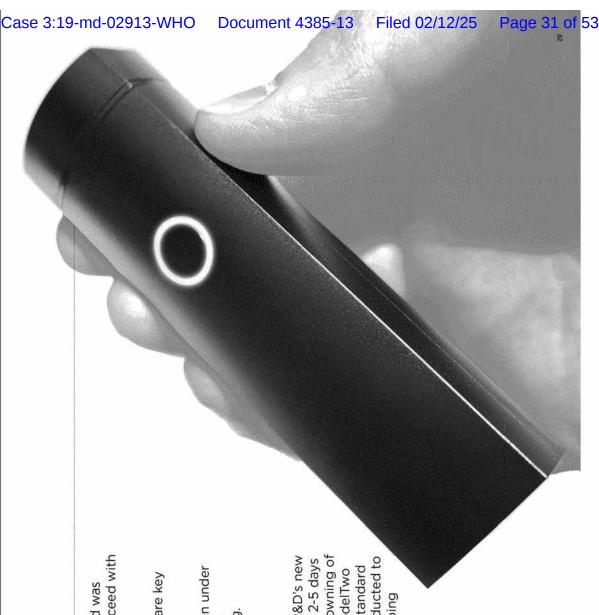
Prototype sample build (shown) in early April with Defond was successful and requires only minor design changes to proceed with engineering sample build in June.

2X battery life and lower enclosure surface temperatures are key improvements over modelTwo.

Mouthpiece ergonomics improved and vapor condensation under mouthpiece reduced through mouthpiece design change. Prototype parts received, tested, and approved for tooling.

Packaging concepts and production quotes received.

Units set to high-temperature (210°C) tested to support R&D's new pod formulation to increase vapor production. Testing for 2-5 days displayed no degradation to plastics and magnets, but browning of heater surface. As a reference, examination of existing modelTwo heaters also shows similar browning of heater surface at standard temperature (180°C). Longer term heating test being conducted to assess any other reliability concerns. We are also prototyping higher-temp heaters with several alternative vendors.



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Pax2





need to package country-specific AC adaptors and allow

us to optimize and unify the packaging.

charging speed being prototyped. This will eliminate the

USB-powered dock with internal battery to maintain

durability, and slow charging. Ul improvements for temp-

mouthpiece removal, light-pipe isolation, drop test

Product is being redesigned for Beta to improve

set, heating and charging status being prototyped for

internal testing. Beta units on track for end of June.

reduced size, better cleanability and product reliability

have been proven out by Alpha prototype testing.

Design improvements over Pax of faster heat-up time,

Charging contact on rear replaces visible screw

Plastic oven lid and smaller, deeper oven

Four independently controlled LED's

Fixed mouthpiece (removable) also serves as On button

Working Alpha prototype shown.

Sealed temp-set button under removable mouthpiece



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R&D and Engineering are working together to create an on-demand, flat heater system.

prototype (approx. 100W/heater) resulted in damage to heater Prototype 1: 3 second heat-up time on over-driven flex heater

Prototype 2: 2.5 second heat-up time on 1.2 sq. in. stainless steel foil heater at 100W/heater (83W/sq. in.) with no damage to heater

Prototype 3: Larger, more usable 2 sq. in. SS heater tested at lower power of 80W/heater (40W/sq. in.) resulted in 6 second heat-up

collaborating with flex heater vendors to improve high temperature Next steps: Now that we have a better understanding of the power heat-up time possible using available battery technology. Path 2 is development paths. Path 1 is to optimize the SS heater geometry, support materials, and oven construction to achieve the fastest characteristics of SS foil heaters, we are pursuing parallel

system that will optimize the user experience with an on-demand In tandem, R&D is exploring a disposable pouch-based tobacco flat heater system



Filed 02/12/25

## timeline overview

	Timing	Completed mid Oct. 2013	Completed Feb 2014	Started Feb 2014	Delay to July 2014	Oct 2014	Nov 2014	Nov 2014	Dec 2014	Jan 2015	Feb 2015	March 2015
Juul	milestone	Functional prototypes (5 devices/20 pods)	Alpha prototypes (25 dev/100 pods)	Design / liquid / pack design start	Beta devices (25 dev/100 pods)	Prototype sample build (50 dev/200 pods)	Packaging design (final)	Engineering sample build (100 dev/400 pods)	DVT build (200 dev/1K pods)	Pilot production (250 dev/1K pods)	Mass Production Start	Ready for market launch
	timing	n/a	Completed May 2014	Started May 2014	Jun 2014	Sep 2014	Oct 2014	Oct 2014	Nov 2014	Dec 2014	Jan 2015	February 2015
Pax2	milestone	Functional prototypes (1 device)	Alpha prototypes (3 devices)	Packaging design start	Beta devices (5 devices)	Prototype sample build (25 devices)	Packaging design (final)	Engineering sample build (50 devices)	DVT build (200 devices)	Pilot production (250 devices)	Mass Production Start	Ready for market launch
	timing	Completed mid Oct. 2013	Completed Feb 2014	Started Feb 2014	n/a	Apr 2014	Jun 2014	Jun 2014	Aug 2014	Sep 2014	Sep 2014	October 2014
modelThree	milestone	Functional prototypes (1 device)	Alpha prototypes (5 devices)	Packaging design start	Beta devices	Prototype sample build (50 devices)	Packaging design (final)	Engineering sample build (100 devices)	DVT build (200 devices)	Pilot production (250 devices)	Mass Production Start	Ready for market launch
	phase.	-	2		2	4						2

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R&D develops core technologies that enable products consumer satisfaction and market differentiation. with a significant improvement in vapor quality,

Establish an industry-leading scientific understanding of aerosol science and chemistry for e-vapor products.

Continuously create new technical solutions with a clear view towards productization.

#### key learnings

Taking a novel approach to the problem of vapor production in Pods has led to a significant improvement.

Case 3:19-md-02913-WHO

JUUL flavor development is progressing slower than anticipated.

#### key initiatives

Prepare development timeline for Pods improvements by end of May

**Document 4385-13** 

With FDA deeming regulations recently released, develop a position on regulatory environment and implications for Ploom.

Complete clinical study of JUUL nicotine chemistry by mid June.

Set new agreements and practices to address IP expenses by end of May

Filed 02/12/25

Implement new approaches to flavor development for JUUL

Develop new tobacco pouch concept that's compatible with rapid heating ("BOOX") concept by end

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MDL RV0000289

#### Pod Improvements

existing humectants (PG and VG). These improvements were presented to the JTI Ploom R&D developed two alternatives for improvements to vapor production in ingredient: trimethylene glycol (TG). The second requires a shift in the ratio of Pods. The first, and preferred, option requires the use of a new humectant Emerging Products team on April 2.

approved. Ploom and JTI therefore resolved to focus on Option 2, while continuing requested. For Option 2, the requested shift in humectants was preliminarily insufficient published toxicity data to support the usage of TG at the levels For Option 1, subsequent assessment by JTI SRA deemed that there was to investigate Option 1 for later introduction.

obtain the full benefit. Ploom and JTI are now working to determine development For both options, an increase in the device operating temperature is required to Model 3 launch (targeted October 2014). We aim to have this timeline ready for timelines, such that the Option 2 improvement can be implemented in time for review with all relevant Ploom departments by June 1.

#### JUUL Clinical Study

The R&D team visited the New Zealand site where the JUUL formulations study is development. Preliminary data supports the claims of improved nicotine delivery being conducted. The purpose of this study is to support our patent filings with industry standard pharmacological data, as well as to further guide product relative to e-cig formulations currently on the market.

#### Flavor Development

added a qualified new flavor house to our list of partners (now totaling 3), and are R&D is bolstering efforts in flavor development for JUUL liquids. Specifically, we exploring new approaches based on mimicry / reverse engineering of flavors already successful in the marketplace.

#### New Tobacco Platform

with Ploom PD, yielded two promising first prototypes. R&D will continue to focus on this effort, and in addition has begun to develop ready-made tobacco pouches Development of a tobacco-based rapid heating system ("BOOX"), a collaboration

### In-house Analytical Capabilities

loop for various development efforts. Regulatory

quantify nicotine and other compounds of interest. This will speed up the feedback

A UV/Vis spectrophotometer was purchased, and methods have been validated to

position on potential implications for Ploom's current and planned new products. The main near-term action item is to advocate our views in the 75-day comment Proposed FDA deeming regulations were released April 24. R&D is developing a period.

JUUL: Conversion of formulations provisional filed.

Pods: Claims granted for key features of the device and cartridges in Japan and Europe (702 Family).

PAX: Trademark registration for the 'X' symbol and for BLEND X.

IP legal fees exceeded budget in Q1. In response we will establish a new capped fee scheme by end of May.

#### Counterfeiting

effective at increasing enforcement by B2B/B2C sites such as Alibaba and DHGate. This supports that PR can be a cost-effective measure in combatting counterfeits. A cover article in Tobacco International exposing PAX counterfeiting has proven

Counterfeit PAX sales outside the U.S. are observed to be increasing, with high incidence in Spain. A brief is being prepared for JTI's review.

No counterfeit activity for M2 or Pods has been reported yet.

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### 2014 Goals & Milestones

Ploom R&D will continue development and refinement of overall formulations, including our own unique nicotine chemistry, for use in the U.S. market.

- Apr Preliminary selection of functional ingredients
- June Complete clinical study of JUUL formulations, to confirm delivery profile and support patent applications
- Aug Complete stability study of formulations in JUUL cartridges
- Oct Flavor development complete

made and loose-leaf tobacco categories. The latter will be prioritized, to preserve In addition, Ploom sees the opportunity to develop new platforms in the ready-Ploom's leader position in the category.

- Apr Proof of concept for fast heat-up loose-leaf vaporizer
- Jun First round prototype
- Aug Develop new product spec with Engineering, Sales, and Marketing
- Sep Translate learnings for a new ready-made platform
- · Dec Proof of concept for a new ready-made platform

### 2015 Planning

To identify new areas of investigation for 2015, Ploom R&D will in 2014:

- Conduct panel discussions with all relevant internal departments (Marketing, Sales, PD, Customer Service)
- Consult with industry experts (both e-cigarette and traditional tobacco)
- Identify FTO and areas for IP capture with patent counsel
- Topics to be presented for discussion at Q3 and Q4 BOD meeting
- Development plans to be finalized by EOY 2014

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Current prioritization of new topics:

Wick- and coil-less e-cigarette

2. Multiple heaters with selectable flavor, vapor production, or nicotine strength

3.Thin film tobacco

4.Tobacco extract-based e-liquid flavors

5. Powerless aerosolization

**Staffing:** To support the breadth of new projects in 2015, as well as ongoing support for products in engineering and post-launch, R&D anticipates 4 new hires in 2015 within key disciplines (See EOY 2015 org chart).

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R&D growth

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# customer service

Great customer service is a sellable product. It's brand reputation and product value, validated in the eyes of the customer.

support a seamless end-to-end customer experience. CS focuses on world class customer service but also manages the front and back end of the website to

CS is a centralized resource for the entire company to gather consumer insights, empathy and useful analytics.

### key learnings

Ploom customer service and warranties are key purchasing decisions for customers and consumers.	Rapid growth and distribution adds complexity to growing customer base	More work is needed to accommodate online sales of tobacco products and to accurately capture e-commerce operational costs.	Service and support opportunities exist between customer/consumer facing departments.
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### key initiatives

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## Lead CRM and database implementation

## Ensure site operations are efficient and effective.

## Build internal support structure

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Sum of department initiatives: ensuring exceptional customer experiences and services are delivered in every interaction.

The CS department has reached the ceiling of what's achievable with current software solutions; we are meeting customer expectations, but not exceeding them. The features below do not exist in our current software solutions.



- Complexity of B2B and B2C support services requires interdepartmental communication
- Streamlined platform that promotes external/internal customer and consumer communications



- Luxury services for a luxury brand
- · Create insightful customer profiles for personalized service, e.g. VIP's, returning customers, different product users
- Greater knowledge could be achieved by tracking customer purchase decision history.
- Quick access to total customer history for improved message quality
- · Warranty services are manually received, sorted and processed, accounting for 25% of our volume and 50% of our labor costs.
- Automate rote and manual workflows for quicker warranty service turn around

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## customer service

Sum of department initiatives: ensuring exceptional customer experiences and services are delivered in every interaction.

E-commerce operations have previously been spread across departments adding to unknown costs. New online tobacco regulations have added to the complexity of e-commerce operations and cost.

Ploom.com initiative: maximize only direct to consumer channel and highest margin

- 3-4% of ploom.com monthly revenue is absorbed by e-commerce merchant services, not identified in previous budgets.
- Identify and assess all site operational costs to inform future strategy and investment decisions
- 25% of all site sales are at risk without optimized credit card processors and age verifications systems.
- Ensure ploom.com is operationally sound and provides a brand worthy consumer experience
- 75% of customer support volume is non-warranty related and could be relived with more site resources.
- Increase customer self service, add visual resources and improve site navigation to alleviate contact overload, ultimately improving response times and quality of service.

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## customer service

Sum of department initiatives: ensuring exceptional customer experiences and services are delivered in every interaction.

CS, Marketing and Sales cover 7 external communication channels with no process for consistent support and messaging across those channels.

Internal Support Structure: Foster dynamic touch points between CS, Marketing and Sales

- Identify Marketing and Sales counterpart positions in CS to align communication strategies
- Social media messaging aligned with proactive support outreach
- · Retail advocacy messaging aligned with direct to retail service offering
- E-commerce strategies aligned with revenue driving marketing initiatives
- · Direct to consumer support messaging aligned with brand ideals



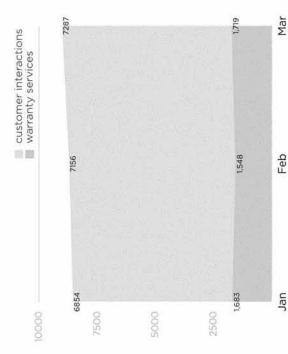


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# customer service: warranty snapshot

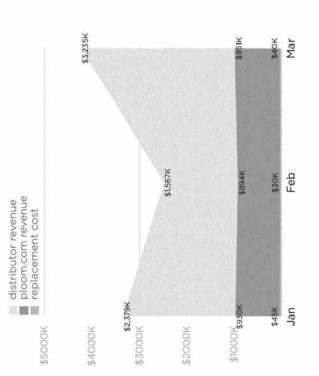
Customer service launched a post warranty survey and the feedback was overwhelmingly positive.

transaction. Others could learn from your @Ploom @D90M49 had a issue and your folks made good. Smoot and easy customer service. Big Pappa Puff @NORMLchaupport 06:54 PM - 23 Apr 14



Warranty service volume and product cost remain low while sales and customer correspondence increase.

Warranty services make up 25% of support request volume Cost to replace devices < 5% of ploom.com revenue



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## Current Sales Expansion Implement test markets

\*Includes 4 people each in LA, SF and NY Metro Staffing for initial sales test markets complete

Includes 2 strategic account managers

- Plan includes 12 additional sales hires this year, dependent on market Success is measured by device/pod ratio and revenue generation results
- Consistent with bplan, sales will be 35% of total headcount at year end, and represents 95% of all intended future hires

Pace of hiring has slowed as all departments have achieved functionality Monthly salary costs forecast below previous projections at \$400K by Hiring plans continue to evolve and adjust based on business needs year end

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Majority of open positions are entry level coordinator roles to improve operational effectiveness of each department

### Personnel Update

CFO hire continues to be highest priority Head of People and Talent (HR) hired COO role being further refined **Test Engineer hired** 

Sales coverage of 17,000 outlets, Q1, 2015

### Phase C

Sales coverage of 45,000 outlets, Q2, 2016

**Phase D** Sales coverage of 70,000 outlets, YE 2017

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### FDA Guidelines - Interpretation and Impact for Ploom

### **Executive Summary**

FDA's proposed deeming regulations were published April 24. FDA will review comments, and is expected to approve final regulations in 2015.

### Expansion of Enforcement to Ploom Categories

- FDA already had jurisdiction over all tobacco products (HR1256), but this
  expands enforcement from cigarettes to all tobacco categories including
  pipe tobacco (Pods / Model 2 platform), e-cigarettes (JUUL platform), future novel consumer tobacco products, and some or all cigars. Enforcement
  applicability to Pax will require clarification by FDA.
- Most importantly, enforcement entails pre-market approval for new products, and post-market approval for products which are on the market but which launched after the grandfather date.
- Enforcement also entails other key provisions including warning labels, no sales to minors, listing of ingredients, and manufacturing audits.
- Limitations on flavors and advertising will likely be addressed in future legislation, but were not included in the proposed regulations.

### Implication for Ploom: Freedom to Operate Issues

- E-cigarettes on the market as of the date of approval of the deeming regulations will most likely obtain relief from FDA market review requirements, possibly through introduction of Congressional legislation. Thus it is important that JUUL not slip in its launch date, and possibly an accelerated launch should be considered.
- Pods have exposure to risk of being removed from the market in 4-6 years, unless Ploom can piggyback on the relief efforts for e-cigarettes. In parallel, Ploom should consider applying for "modified risk" designation so that it can more fully communicate the benefits of Pods to consumers and thus expand sales.
- It is Ploom's view that Pax, as a stand-alone device, should be considered a
  tobacco "accessory" and thus exempt from FDA enforcement, but we will
  seek clarification from FDA on this. If Pax were required to apply for FDA
  post-market approval, it has a high probability of success of being considered "substantially equivalent" to tabletop vaporizers and thus allowed to
  remain on the market.
- Potential investment scenarios required to support Ploom's future regulatory submissions are enumerated below.

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### FDA Guidelines - Interpretation and Impact for Ploom

As expected, the FDA published its draft Deeming Regulations extending enforcement of existing regulations on cigarettes (HR1256) to additional tobacco products including e-cigarettes and pipe tobacco. The FDA has taken a scientific and pragmatic approach in this regulation, applying a broad spectrum view for risk assessment, particularly around new products.

Although this regulation is only at the proposal stage, it provides some clarity and freedom to operate while outlining generally some appropriate restrictions. For the time being, nothing has changed in the current business environment or legal landscape and states continue to pursue local restrictions and limitations across the category.

### Categories Covered by Deeming Regulations

- 1. Require pre-market approval applications (or post-market for products already on the market)
- 2. Prevent adulteration and misbranding
- 3. Provide ingredient lists for tobacco products
- 4. Report harmful and potentially harmful constituents
- 5. Register products with the FDA
- 6. Prohibit modified risk descriptors
- 7. Prohibit free samples
- 8. Enforce Minimum age restrictions
- 9. Require health warnings
- 10. Manufacturing facility inspections

### Paths to Market

Paths are still consistent with HR1256. All products need to register with the FDA following one of these pathways:

- Grandfathered: a product on the market as of 2/15/2007 can stay on the market with no FDA approval required
- Substantial Equivalence: demonstrate a product has the same constituents or poses no new health risks as a product already on the market as of Grandfather date
- New Product Application
- Modified Risk: demonstrate a product reduces harm or risk of tobacco related diseases and is expected to benefit the health of the population as a whole.

### Possible Modifications to the Existing Proposal

At the request of the White House OMB, FDA also evaluated several alternatives, noting however that they may not be legally permissible. However they may anticipate Congressional actions. Two of these alternatives could positively impact Ploom FTO:

Exempt newly deemed categories from premarket submission requirements. (FTO for all current and future Ploom products)

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 Change new product Grandfather Date to the Date of Issuance of a Final Deeming Regulation. (FTO for all current Ploom products, possible SE pathway for future Ploom products)

 Other alternatives would decrease labeling requirements but would not modify Grandfather Date.

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### Enforcement Timeline (as currently written):

Ploom anticipates a 3-6 year freedom to operate window before final regulations are in place and the above restrictions are fully enforced on Ploom

- 75 day comment period has commenced
- 12-24 months before comments are fully reviewed, incorporated and final deeming regulations are published as law
- Once finalized, additional timelines (6-24 months) apply for enforcing each regulatory requirement
- Small businesses (<350 FTE) have an additional 24 months to comply</li>

### Regulatory Context

FDA submissions by definition entail risk, because FDA has the latitude to interpret the relative benefit and risk of the product and to approve or deny any application at its discretion. In the medical device and pharmaceutical industries, there are well defined guidelines for submissions, and a large database of previous applications, and yet many submissions are rejected each year, some relatively unexpectedly from the investor perspective.

That said, a well crafted submission strategy and application package can significantly increase the odds of approval. The regulatory goals of Ploom are to optimize the odds of approval and freedom to operate, to increase commercial potential for its products through being able to communicate their benefits to consumers, and to maintain compliance with regulations once on the market.

The only tobacco products which do not have exposure to approval risk are grandfathered products, and so this is the preferred designation to have. Currently, all tobacco products share a Grandfather Date of Feb 15, 2007. FDA has indicated that it does not have the authority to change the Grandfather Date for e-cigarettes, but in response to the White House it has contemplated (footnote) scenarios in which the Grandfather Date is extended to the Date of Approval of the Deeming Regulations (DADR), or extended indefinitely. There are many potential scenarios regarding Grandfather Date, but currently the most likely scenario is that Congress will extend the Grandfather Date to Date of Approval for Deeming Regulations (DADR), for the e-cigarette category. This date is most likely approximately 1 year away, but could be anywhere from 6 to 24 months away. The investment community continues to believe that the e-cigarette category will maintain freedom to operate, at least for products currently on the market.

Products already on the market as of DADR, or entering within 2 years afterwards have the freedom to enter the market without any FDA submissions. However by the DADR + 2 years point, these products will need to submit either a Substantial Equivalence (SE) or New Product (NPA) application, and after a review of 6-12 months, FDA could have the ability to deny the application and force it off the market immediately, or could approve the product.

Products launched after the DADR + 2 year date would not be allowed to enter the market until FDA approved an SE or NPA application.

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# Submission Pathway for Vaporization Products

For vaporized tobacco products, it is not yet clear what level of evidence the FDA will ultimately require in order to submit an application with an optimized probability of approval. The range of potential scenarios is described below. A more extensive application will require more resources to support it.

		Submission Pathway for Vaporization Products	vay for Vaporiza	tion Products	
Submission / Characteriza- tion Requirement	Substantial Equivalence (Streamlined)	Substantial Equivalence (Extensive)	New Product Application (Streamlined)	New Product Application (Extensive)	Modified Risk
Manufacturing / quality inspec- tion	Post approval	Post approval	Post approval	Pre approval	Pre approval
Ingredients characterization	Yes (for product and predicate)	Yes (for product and predicate)	Yes	Yes	Yes
Vapor constituents / particle size / density	ON	Yes (for product and predicate)	Maybe	Yes	Yes
Animal toxicity studies	No	Maybe	Maybe	Yes	Yes
Stability studies	No	Probably not	Maybe	Maybe	Yes
Human nicotine pK	No	Maybe	Maybe	Yes	Yes
Human biomarkers	No	Maybe	Probably not	Maybe	Yes
Human health effects (tobacco related diseases such as COPD, ung cancer, etc.)	No	No	No	No	5 yrs after it gets on the market
Population effects (smoking initiation, quitting)	No	Probably not, but may increase odds of ap- proval if included	Maybe	Maybe, but may increase odds of approval if included	Yes
Resources to file submission (approximate	nproximatel				- 833
Time to prepare	2 months	6-18 mo	6-18 mo	12-24 mo	18-36 mo
FTE (additional)	1	2	2	3	4
External expenses	<\$200k	\$500k - \$1M	~\$500k - \$2M	\$2M-\$5M	~\$10M
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Unlikely	Possible	Probable
requirement	requirement	Requirement

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## Impact for Ploom and Actions to Consider

		Path to Market		Actions for Ploom to consider
	Grandfathered or Not Enforced	Can enter market but need to file	Need to file before market entry	
Pax Platform			TO THE REAL PROPERTY.	
Blend X	N/A	Blends launched through 2017	Blends launched after 2017	Expect "streamlined" SE application. No action needed for now.
PAX Vaporizer	All PAX, if pipes are "accessories"	All PAX launched through 2017, if pipes are "components"	All PAX Jaunched after 2017, if pipes are "components"	Ask FDA to confirm that Pax is an "accessory" and therefore not enforced. If Pax is deemed "component" then use tabletop vaporizer as SE predicate. Could be "streamlined" or "expanded" SE.
Model 2 / Pods	Pods Platform			THE RESERVE THE PROPERTY OF THE PARTY OF THE
Pods	Pods if grandfather date extended for va- porization, not just e- cigs	Blends launched through 2017	Blends launched after 2017	Lobby for Congress / White House to extend Grandfather Date for all vaporized products, not just e-cigs.  Longer term consider modified risk path to allow Ploom to communicate the product benefits to consumers and
Pod Vaporizer	M2, M3 if grandfather date extended for va- porization	M2, M3, M4 if launched by 2017	Blends launched after 2017	increase sales
UUL Platform				
Harvey Bottles	Harvey – if grandfather date extended for e- cigs	Harvey, if grandfather date not extended for e-cigs	All e-liquids launched after 2017	Maintain on market until launch of JUUL Kit to maintain predicate. Consider increasing sales volume.
JUUL Pods	J1 if grandfather date extended	J2, J1 if grandfather date not extended	)3	Monitor industry efforts to extend Grandfather Date. Consider accelerating J1 launch, and prevent any delays.
JUUL Kie	J1 if grandfather date extended	J2, J1 if grandfather date not extended	)3	If grandfather date does not change, try to get separate SE approval for Harvey, and for Juul Kit with c. 2007 eliquid, and then try to get SE for the combination.
	No restrictions on Freedom to Operate	Risk of FDA removing product from market if found not Substantially Equivalent or if New Product App is denied	Can't enter market without FDA OK	

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